UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF SCOTT SERELS, M.D.

Defendants, Ethicon, Inc. and Johnsons & Johnson (collectively "Ethicon" or "Defendants") submit this Response in opposition to Plaintiffs' motion to exclude or otherwise limit the opinions and testimony of Dr. Serels.

INTRODUCTION

Plaintiffs' Motion challenges neither Dr. Serels's expertise as a urologist/urogynecologist nor his clinical experience with pubovaginal slings. *See generally* Ex. C at pp. 1-2, Ex. D.[1] Plaintiffs do not mention Dr. Serels's board certification in urology and female pelvic medicine and reconstructive surgery. (Ex. D, p. 3). Dr. Serels has worked on clinical trials for pubovaginal slings, has surgically implanted "100's of pubovaginal slings using all sorts of approaches," and has "vast experience as a researcher and clinician." (Ex. C, pp. 1-2). Dr. Serels has also authored numerous publications related to pubovaginal slings. *See* Ex. D, pp. 5-8. There can be no

[1] All references to Exhibits refer to the Exhibits to Plaintiff's Motion, unless otherwise indicated.

question that Dr. Serels is qualified to provide expert opinions on the clinical use and placement of the TVT device.

Despite Dr. Serels's qualifications, experience, and review of medical literature, the TVT device IFUs, and professional education materials, Plaintiffs seek to preclude Dr. Serels from testifying about the adequacy of the TVT IFU, alternative treatments for stress-urinary incontinence ("SUI"), and mesh design. Specifically, Plaintiffs claim that

1. Dr. Serels is not qualified to offer opinions on degradation, cytotoxicity, or mesh design generally, including the significance of laser-cut versus mechanically cut mesh.

2. Dr. Serels offers no reliable basis for his opinions on degradation, cytotoxicity, or mesh design generally, including the significance of laser-cut versus mechanically cut mesh.

3. Dr. Serels is not qualified to speak to the adequacy of the TVT IFU and has no reliable basis for his opinions regarding the TVT IFU.

4. Dr. Serels has no reliable basis for his opinions regarding alternative treatments for SUI.

5. Certain of Dr. Serels's opinions constitute legal conclusions.

6. Certain of Dr. Serels's opinions are irrelevant and inflammatory.

For the reasons set forth below, Plaintiffs' arguments fail. Plaintiffs have cherry-picked statements out of context, have mischaracterized Dr. Serels's testimony and report, and otherwise have no basis for their claims. The Motion should be denied.

ARGUMENT

I. Dr. Serels is not offered as a biomaterials, chemical engineering, surgical pathology, or polymer chemistry expert.

Plaintiffs argue that Dr. Serels should not be allowed to offer opinions on the mesh design generally, as he is not a biomaterials, chemical engineering, surgical pathology, or polymer chemistry expert. However, Dr. Serels *is* an expert in the clinical application and

implantation of mesh products, including but not limited to the knowledge of a board certified urologist regarding the healing process, overall success rate, and complications with SUI mesh products.

The opinions Plaintiffs object to are (1) "[t]he TVT's design and material is reasonably safe for its intended use," (2) the mesh does not undergo particle loss or degrade, (3) there is no clinical difference between laser cut and mechanically cut mesh, and (4) claims of "adverse systemic effects associated with alleged cytotoxicity . . . are not accompanied by any methodologically sound or scientific analysis, and is [sic] completely lacking in clinical significance." Ex. C, pp. 2, 14; Ex. B, 104:1-105:19. Each of these opinions is well-supported, reliable, and admissible.

Nowhere does Dr. Serels suggest that he will discuss the design of the product in terms of Ethicon's protocols, FDA requirements or regulations, chemical content or polymer structures. Nor does his Report or testimony indicate that he intends to opine on failure modes effects analyses as related to product design. Plaintiffs' Memorandum at 5. Rather, Dr. Serels's opinions rely on his years of education and experience related to the pelvic floor anatomy and the use of mesh to treat SUI, as well as on his clinical observations in performing thousands of surgeries with polypropylene mesh slings, including both implants and explants of the devices, and his extensive review of scientific literature. Ex. C, pp. 2, 13-14.

Plaintiffs are attempting again to create a strawman argument that simply is an inaccurate representation of Dr. Serels's opinion. As Dr. Serels states in his Report, "My opinions are based on my vast experience as a researcher and clinician as well as the knowledge of the literature." Ex. C, p. 2. Dr. Serels has expertise to testify as to whether the design of the devices was adequate to address the conditions for which they were being used, i.e., he can address the design

in terms of the efficacy of these devices in treating SUI. *See, e.g.*, Ex. C, pp. 12-13. His opinions are related more to the efficacy of the device than a *per se* design opinion, and he is able to identify and explain that the design of the TVT products was effective in treating his patients for SUI. He also cites clinical data supporting his conclusion that TVT products were effective to treat his patients. *See* Ex. C., pp. 9-10. Dr. Serels further has experience with other similar products, from manufacturers other than Ethicon, and has helped develop the products, has conducted research, and has "published and taught extensively on the use of slings" for many years. Ex. C, p. 2.

Finally, to the extent Plaintiff claims Dr. Serels's opinions on the risks and benefits of TVT devices for treatment of SUI lack support, which Ethicon disputes, these claims are better addressed on cross examination than by excluding testimony. *Trevino v. Boston Scientific Corp.*, Memorandum Opinion and Order (*Daubert* Motions), No. 2:13-cv-01617, 2016 WL 1718836, *23 (S.D. W. Va. April 28, 2016).

A. Dr. Serels's opinion that "[t]he TVT's design and material is reasonably safe for its intended use," is well-supported, reliable and admissible.

In his Report, Dr. Serels describes various historic and current treatments for SUI and refers to pubovaginal slings as "the gold standard." Ex. C, pp. 8-10 (citing clinical success rates using pubovaginal slings). Dr. Serels describes six (6) design features of these slings that support his opinion and further describes improvements to the design that minimize complications from surgery. *Id*. at p. 8-10. Dr. Serels describes the use of the single incision sling (SIS) technique as having "demonstrated relatively high success rates with minimal morbidity." *Id*. at pp. 9-10 (citing clinical data, including success rates and complication rates). Dr. Serels draws from his clinical experience and the relevant medical literature to determine that the product benefits outweigh the product risks; he further notes the development of new surgical techniques to

decrease the risks of implanting the devices. This Court has determined that such experience is sufficient for opinions of this nature. *See Trevino* 2016 WL 1718836 at *6.

Given his experience, and the opposing opinions of Plaintiffs' experts that are also based on their experience, it is reliable and relevant for Dr. Serels to testify that, in his hundreds of uses of these products, the design was efficacious in treating difficult pelvic floor disorders.

B. Dr. Serels's opinion that the mesh does not undergo particle loss or degrade is well-supported, reliable and admissible.

Dr. Serels testified that a significant portion of his practice, approximately five percent, is related to treating complications from pelvic mesh procedures. Ex. B, 38:17-20. "People are sent to [Dr. Serels] specifically to have their complications remedied, such as erosion or a problem with mesh." *Id*. at 37:24-38:8. He has explanted at least 200 mesh products during the course of his career. *Id*. Dr. Serels's Report notes that the "claims of alleged particle loss and mesh degradation . . . are not supported by any level 1 evidence," and he has not "experienced any complications attributable to alleged particle loss or degradation in my 20 years of clinical practice." Ex. C at pp. 14-15 (noting that "[t]he choice of a macroporous, monofilament, polypropylene mesh tape as the most suitable material for use in mid-urethral slings is substantiated by strong clinical data" and rejecting Plaintiffs' experts suggestions "that TVT implantation results in carcinogenic effects or adverse system effects," as those "claims are not accompanied by any methodologically sound or scientific analysis").

As in the Court's ruling in *Huskey*, Dr. Serels's opinion is based on both his personal experience and his review of medical literature. Dr. Serels specifically cites his review of literature and notes that, in fact, there is *no* reliable evidence showing particle loss and/or degradation. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 734-35 (S.D. W.Va. 2014)

("[D]rawing on clinical experience and a review of relevant literature is a sufficiently reliable method of forming this particular opinion.").

C. Dr. Serels's opinion that there is no clinical difference between laser cut and mechanically cut mesh is well-supported, reliable and admissible.

Similar to the above arguments, Dr. Serels's observations are plainly based on his experience as a clinician and review of the pertinent medical literature. "Ethicon still sells both mechanically cut and laser cut TVT in order to satisfy surgeon preferences. There has been rigorous clinical data from implants prepared using the 2 different techniques. There has been robust opportunity to assess for any difference in outcomes. None have been observed." Ex. C at pp. 14-15; Ex. B at 153:1-4 (citing his review of level one literature and responding that there is no such evidence supporting "any difference in outcome or complication rate between laser cut mesh and mechanically cut mesh").

Dr. Serels's testimony on this point does not contradict his Report. *See* Ex. B at 103:14-105:19; 152:14-153:4. Plaintiffs attempt to make much of Dr. Serels's agnosticism with respect to how the mesh was cut, but Dr. Serels is plainly of the opinion that whether a TVT device is "mechanically cut or not, it's of no consequence" *Id*. at 104:18-19. Dr. Serels, an experienced clinician, has observed no discernible difference between the laser-cut and mechanically cut mesh in his practice or in the level one literature.

D. Dr. Serels's opinion that claims of "adverse systemic effects associated with alleged cytotoxicity . . . are not accompanied by any methodologically sound or scientific analysis, and is [sic] completely lacking in clinical significance" is well-supported, reliable and admissible.

Dr. Serels's Report cites to the long history of polypropylene mesh for medical uses. Ex. C at 14-15. Despite Plaintiffs' claims that Dr. Serels failed to review Plaintiffs' experts' reports and literature cited therein, the Report plainly states, "Plaintiffs' experts have also suggested that

TVT implantation results in carcinogenic effects or adverse systemic effects associated with alleged cytotoxicity. These claims are not accompanied by any methodologically sound or scientific analysis, and is [sic] completely lacking in clinical significance." Ex. C at 14. That Dr. Serels considered and rejected the opinions of Plaintiffs' experts is not sufficient reason to disqualify his opinion; it is, in fact, ripe for cross-examination.

Even if Dr. Serels omitted citations to particular documents in forming his opinions, that is beside the point. Neither was he questioned by Plaintiffs about any particular documents he rejected when they had the opportunity to do so at his deposition. This court has repeatedly rejected such challenges, and held that if plaintiffs take issue with an expert's "failure to review or cite particular documents, this goes to the weight of his opinion, not its admissibility, and can be addressed on cross-examination." *See Sanchez v. Boston Scientific Corp.*, 2014 U.S. Dist. LEXIS 137189 at *78 (S.D.W.V. Sept. 29, 2014) (holding that the plaintiff's contention that an expert "selectively cited several articles" and "failed to include contrary statements or literature in his report" could be addressed on cross-examination.) As in *Sanchez*, Dr. Serels should be allowed to offer his opinion, subject to cross-examination based on the allegedly contrary literature.

II. Dr. Serels is qualified to address the adequacy of the IFUs and Ethicon's warnings based on his clinical and research experience and supporting literature and studies.

Ethicon writes its IFU for pelvic floor surgeons like Dr. Serels. Under the learned intermediary doctrine, surgeons like him are the ones who must be adequately warned. In fact, the IFU says that "the device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the [device]," TVT IFU, Ex. A at 2. If Plaintiffs intend to argue at trial that Ethicon's IFU failed to disclose certain risks, Ethicon is

fully entitled to defend such claims by demonstrating that those risks were obvious to the users of the product (pelvic surgeons), and therefore, did not need to be disclosed.

As a proctor for TVT, Dr. Serels has taught implantation techniques and discussed the indications and complications with implantation. He has taken part in the implantation sections of various IFU designs. He is well qualified to discuss whether the IFU literature adequately addreses verified complications, as he fully comprehends and manages issues that are both unique to SUI mesh, as well as inherent in any pelvic floor surgery.

Ethicon recognizes that this Court has previously precluded its experts from opining that a "warning was adequate, merely because it included risks he has observed in his own practice." *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Memorandum Opinion and Order (*Daubert* Motions), Doc. 265 at 35 (S.D. W. Va. Nov. 20, 2014). That is not what Dr. Serels does here. Instead, he opines that risks that Plaintiffs allege should have been in the IFUs are those that a pelvic surgeon would already know. He supports this opinion not only through his own clinical and teaching experience, but also by a review of relevant medical literature. *See* Ex. C, p. 9 (citing his review of the complication and success rates for synthetic slings and noting that "[m]ost of these complications were due to the use of trocars in the retropublic space," a complication from surgery, not the sling). And given the application of the learned intermediary doctrine in these cases and that Ethicon need not warn of risks known to surgeons experienced in pelvic surgery, this testimony is both relevant and not contrary to this Court's prior rulings.

Dr. Serels relies on his experience as a urologist, clinical instructor, and clinical researcher with a subspecialty in pelvic floor surgery to discuss what risks of pelvic floor surgery would be known to such surgeons generally. Ex. B., 154:24-157:10. Because these surgeons would know of these risks, including this information in IFU documents is not necessary. *Id*. at

155:19-24. This relates to adequacy of the IFU because the failure to warn analysis involves a determination of what the user of the product knew. Thus, a surgeon's perspective on what pelvic surgeons know – based upon extensive clinical and teaching experience, as well as supported by scientific literature – directly correlates with risks that do not need to be in the IFU. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (internal quotations and brackets omitted)).

Plaintiffs specifically asked Dr. Serels about lists of risks, including voiding dysfunction, exposed mesh, the need for additional surgical intervention to address complications, bleeding, hematoma, incontinence, urinary frequency, retention or obstruction, acute/chronic pain, neuromuscular problems, dyspareunia that may not resolve, seroma, urge incontinence, adhesion formation, atypical vaginal discharge and death. Ex. B, 128:24-130:22. As to each of these risks (except for exposure/erosion), Dr. Serels noted it was also a risk of any pelvic floor surgery, with mesh augmentation or without. *Id*. at 154:20-155:14.

Because of this, Dr. Serels could state objectively that any failure to include these particular risks in the IFU did not make the IFU inadequate since pelvic floor surgeons know these risks. *See* Ex. B., 155:19-156:10. He further can testify that the lack of inclusion of such risks as adverse events would not "deprive a reader [surgeon] or mislead a reader [surgeon] of what the risks and benefits" of the devices were when the IFUs were published. *See, e.g.*, *Huskey*, 29 F. Supp. 2d at 719 (addressing permissible scope of testimony from plaintiff's expert urologist) (quoting *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000)).

Contrary to Plaintiffs' assertions, Dr. Serels plainly based his opinions on both his clinical experience and his review of the literature. Ex. C, p. 2. He also has "extensive experience teaching residents and fellows on the risks and benefits of surgical treatment for stress urinary incontinence and pelvic organ prolapse, including training on the Instructions for Use (IFU)." *Id*. Dr. Serels also explained that "roping" and "curling" of the TVT mesh "is only possible if after the tape is placed, and the plastic sheaths are removed, significant tension is applied to the ends of the exiting sling in order to tighten the mesh," which is a technique that is "clearly contrary to what is outlined in the surgical steps of the IFU." *Id*. at 15.

Dr. Serels has intimate knowledge of the IFUs; he "helped with the ... procedural steps in an IFU for a device." Ex. B at 31:7-8. While Plaintiffs attempt to paint Dr. Serels's testimony as essentially rejecting IFUs, Dr. Serels actually testified that "as a physician what's written in the IFU is not necessarily as important as what one's peers do and what's published in the literature." *Id*. at 119:6-9. Further, Dr. Serels would use the IFU "as a starting point." *Id*. at 121:10-14. Dr. Serels plainly has sufficient basis for his opinion regarding the adequate disclosure in the IFUs of the specific risks at issue.

Dr. Serels is not offered to testify concerning the regulations applicable to product warnings or whether Ethicon complied with those regulations. Nor will he address internal Ethicon protocols related to product warnings or what risks Ethicon knew when the IFUs were drafted. Rather, Dr. Serels's testimony is based on his perceptions as a pelvic surgeon, his knowledge of what risks a pelvic surgeon would know, and medical literature and studies concerning risks.

Plaintiffs attempt to make much of the fact that Dr. Serels does not know if Ethicon warned of "all known risks," yet this is not the standard under a failure to warn analysis.

Plaintiffs' Memorandum at 11. Nor is it the standard under the governing regulations related to prescription medical devices. *See* 21 CFR § 801.109(c) (applicable to "Prescription devices") (warning need not include "directions, hazards, warnings, and other information [ ] commonly known to practitioners licensed by law to use the device."). This comports with the learned intermediary doctrine as well. Given that a manufacturer has no duty to warn of risks known or obvious to those using its product, the general knowledge of pelvic floor surgeons is the pinnacle inquiry. "All known risks" are not in issue in this case, only those risk specified by Plaintiffs, and Dr. Serels has adequately addressed each of those.

Dr. Serels is competent to testify about how Ethicon's IFUs would be perceived by pelvic surgeons. This Court has recognized that where an expert is not relying on the regulatory standards for warning opinions, addressing risks perceived in clinical practice and whether the warning conveys such risks are within an expert's realm to make the comparison. *Trevino*, at 30. That is what Dr. Serels does here. He evaluated a host of risks that Plaintiffs urge should have been contained in the IFUs and, applying his clinical experience and education, determined whether those risks are ones that pelvic floor surgeons would have known, thus dispensing with the need for a specific warning in the IFU.

Since Dr. Serels is not offering testimony that the IFU was adequate for regulatory or FDA purposes, but instead opines that pelvic surgeons would have known that these risks exist just in performing pelvic surgery, then his opinion that the IFU was adequate when evaluating it from a surgeons' point of view is relevant and reliable.

III. Dr. Serels's Opinions Regarding Alternative Treatments for SUI are Reliable.

Plaintiffs argue that Dr. Serels provides "no explanation" in his Report for his opinions that "complications occur in all procedures for stress incontinence and are not unique to mid-

urethral slings," and that "the TVT appears safer than either the Burch procedure or pubovaginal sling." Ex. C, pp. 13-14. This argument is nearly identical to Plaintiffs' previous arguments that Dr. Serels's opinions, based on his clinical experience and review of the medical literature, are contrary to the opinions of their experts.

First, Dr. Serels's Report contains nearly ten (10) pages of information on SUI treatments and their various risks and benefits. He cites numerous studies supporting these statements. *See* Ex. C, pp. 3-13. He specifically cites the complication and cure rates of various treatments, including the Burch procedure and pubovaginal slings. *See id.* at pp. 6-7, 9-10. Each of the techniques discussed in Dr. Serels's Report has complications, which he describes. *See id.* at pp. 3-13. There can be no question that Dr. Serels's opinions regarding the existence of complications and relative safety of the TVT system when compared to alternative methods are well-supported by his education, clinical experience, and medical literature review.

Second, to the extent Plaintiffs object to Dr. Serels's opinions merely because their experts have come to different conclusions, these claims are better addressed on cross examination than by excluding testimony. *Trevino*, 2016 WL 1718836 at *23. Plaintiffs cannot seek to disqualify Dr. Serels's well-supported and reliable opinions merely because they disagree.

IV. Dr. Serels's Opinions are Neither Legal Conclusions nor Inflammatory

Plaintiffs object to two cited statements by Dr. Serels, that "the TVT's design and material is reasonably safe for its intended use and the Instructions for Use adequately and appropriately warns physicians," and that "I have an intimate understanding of what the reasonably prudent pelvic floor surgeon should know." Plaintiffs' Memorandum at 15. Of course, these are not legal conclusions and are offered as expert testimony regarding Dr. Serels's

experience, education, and review of the medical literature. Plaintiffs may certainly cross-examine Dr. Serels on these points.

Plaintiffs also object to certain allegedly "inflammatory" statements by Dr. Serels. *See* Pl.'s Brief at 15). Ethicon admits that Dr. Serels is not held out to be an expert regarding the effect of litigation on "evolutionary advancements in the treatment of stress urinary incontinence." *See* Ex. C, p. 15. However, Dr. Serels's conclusion, that the polypropylene mesh sling is important to the treatment of SUI and women's health in general, is part of his reliable, well-supported expert opinion.

CONCLUSION

For the reasons set forth above, the Court should deny Plaintiffs' Motion to Exclude or Otherwise Limit the Opinions and Testimony of Scott Serels, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 16, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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